

510(k) Summary (modified)

Prepared: March 29, 1996

K960839

Submitter:

DEC 18 1996

Company Name: Canon USA, Inc.
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Device:

Reason For 510(k): New Model
Manufacturer: Canon Inc.
Trade Name: Canon
Model Name: Film Scanner 300
Classification Name: Image Digitizer
FDA 510(k) #: K960839

Substantial Equivalent Device:

Manufacturer: Vidar
Trade Name: Vidar
Model Name: VXR-12
Classification Name: Image Digitizer
FDA 510(k) #: NOT AVAILABLE

Description Of Device:

The Canon Film Scanner is a desktop size x-ray film digitizing system with CCD linear sensor. Features high throughput due to high speed scan and automatic film feeder with 100 sheet capacity. DICOM and FTP protocol on TCP/IP are supported.

Intended Use:

Both devices are designed to digitize medical images from x-ray film.

Technical Characteristics:

Please refer to the attached COMPARISON CHART.

Non-clinical Tests:

Software evaluation is being performed to show substantial equivalence.

Clinical Tests:

N/A

Conclusions:

Please wait for the completed software evaluation report to be submitted under separate cover.